Supreme Court, U.S.
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No.

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In The

Supreme Court of the United States

October Term, 1994

HELEN GILE,

Petitioner,

vs.

OPTICAL RADIATION CORPORATION; XYZ COMPANIES #1 through #5; JOHN DOES #1 through #5,

Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether this Court intended that its holding in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), be extended by the courts to preempt common law tort claims under another federal statute without first conducting a thorough analysis of the language, purpose and legislative history of the statute.

2. Whether the courts may apply a blanket preemption to all of a plaintiff's claims, ignoring clear language in the federal statute that exempts several of the claims from preemption.

3. Whether hundreds of thousands of elder citizens who were the subject of a medical experiment can be deprived of their constitutional right to claim the protection of the common law when they have been injured by the experimental device.

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OPTICAL RADIATION CORPORATION; XYZ COMPANIES #1 through #5; JOHN DOES #1 through #5,

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Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR WRIT OF CERTIORARI

The petitioner, Helen Gile, respectfully requests that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Third Circuit (the "Third Circuit"), affirming the judgment of the United States District Court for the District of New Jersey (the "District Court"), granting summary judgment to respondent Optical Radiation Corporation.

OPINIONS BELOW

Included in the appendix are orders and opinions rendered on the merits of the plaintiff's claims, to wit: (1) the Judgment of the Third Circuit affirming the Order of the District Court, dated May 3, 1994 [1a], (2) the Opinion of the Third Circuit, dated May 3, 1994 [3a], (3) the Order of the District Court granting summary judgment to defendant Optical Radiation Corporation, dated August 23, 1993 [17a], and (4) the Opinion of the District Court, excerpted from the transcript of the hearing, dated August 23, 1993 [19a].

STATEMENT OF JURISDICTION

The judgment of the Third Circuit was entered on May 3, 1994. This Petition for Writ of Certiorari was timely filed. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

There are many statutory and constitutional provisions involved in this Petition. Pursuant to Rule 12.1(f), these provisions are cited here and their texts are set forth in the appendix.

United States Constitution, 1st Amendment
United States Constitution, 7th Amendment
United States Constitution, 10th Amendment

The Public Health Cigarette Smoking Act of 1969,
15 U.S.C. § 1334

The Food, Drug and Cosmetic Act, 21 U.S.C. § 360g(e)
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New Jersey Product Liability Statute, N.J.S.A. § 2A:58C-2

STATEMENT OF THE CASE

Petitioner Helen Gile filed this action under New Jersey law for compensatory and punitive damages for injuries to her left eye caused by implantation in that eye of a defective intraocular lens (IOL), called the UV11H1 Stableflex anterior chamber IOL, manufactured and distributed by respondent Optical Radiation Corporation.

The Food and Drug Administration (FDA), which regulates intraocular lenses under the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA), granted respondent an Investigational Device Exemption (IDE) on September 17, 1981, with supplements granted thereafter. This IDE permitted respondent to conduct a clinical investigation by eye surgeons to determine whether its Stableflex anterior chamber lenses (models 11H, 11H1, 11H1S, UV11H, UV11H1 and UV11HS) were safe and effective.

Respondent was one of approximately a dozen IOL manufacturers that had received IDEs from the FDA at the time of Mrs. Gile's surgery. Under these IDEs, the various manufacturers sold over one million IOLs, classified by the FDA as "investigational". These lenses were implanted in the eyes of American cataract patients, most of them elderly citizens.

On December 5, 1985, Mrs. Gile underwent cataract surgery during which Dr. Henry A. Scimeca implanted into the anterior chamber of her eye a UVIIHI Stableflex lens manufactured by respondent. Dr. Scimeca was one of more than 3,000 clinical investigators registered to carry out the safety and effectiveness study of respondent's IOLs.

On November 26, 1985, respondent discontinued the sale of Stableflex IOLs. On December 19, 1986, respondent informed the FDA that all implantations of Stableflex lenses would be suspended and in 1987, respondent formally terminated the clinical investigation.

Approximately 65,000 Stableflex lenses were implanted into the eyes of our elderly citizens during the course of the clinical investigation, of which about 57,000 were UV models. Of the patients receiving UV lenses, more than 500 suffered acute corneal decompensation (serious damage to the cornea). More than 300 patients required corneal transplants.[1]

On September 16, 1987, respondent's lens was surgically removed from Mrs. Gile's left eye. Mrs. Gile is now legally blind in that eye. Her best corrected vision is 20/400.

In her complaint, included in the appendix at 26a, Mrs. Gile alleged that the respondent (l) breached express warranties and implied warranties of merchantability and of fitness for a particular purpose, (2) acted negligently in designing the lens, in testing, manufacturing, distributing and marketing it, in inadequately monitoring the investigational study of the lens, in

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1. In 1979, the National Institutes of Health reported that about 100,000 lenses were being implanted annually by some 4,000 eye surgeons. National Institutes of Health, *NIH Consensus Development Summary, vol. 2, no. 7: Intracolar Lens Implantation* (1979).

disseminating incomplete and misleading information to the medical community and the public about the lens, in failing to properly warn patients and physicians about the hazards of the lens, and in failing to withdraw the lens from the market when it became clear that its risks were unreasonably high, (3) is strictly liable in tort for placing a defectively designed and manufactured lens on the market without adequate warnings and instructions, and (4) fraudulently misrepresented the safety of the lens in communications with the public and the medical profession.

Respondent filed a motion for summary judgment based on the doctrine of federal preemption and on Section 521 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k. The District Court granted summary judgment to respondent, holding that the preemption provision of the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act preempted state common law tort claims. Mrs. Gile appealed and the Third Circuit affirmed the District Court's ruling, holding that pursuant to the United States Supreme Court's decision in *Cipollone v. Ligget Group, Inc.*, 112 S. Ct. 2608 (1992), the use of the term "requirement" in the preemption provision of the MDA referred to common law tort claims as well as legislative enactments.

REASONS FOR GRANTING THE WRIT

The interpretation given by this Court to the term "requirement" in the Public Health Cigarette Smoking Act should not be applied to another federal statute without a thorough analysis of the language, purpose and legislative history of the statute. The district courts and the courts of appeal have extended this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), beyond its limited meaning, depriving thousands of elder citizens of their constitutional right to seek redress for injuries received in a medical experiment, and this is an important question of federal law which should be settled by this Court.

I.

THE COURTS SHOULD NOT BE PERMITTED TO EXTEND THIS COURT'S RULING IN *CIPOLLONE V. LIGGETT GROUP, INC.* TO ANOTHER FEDERAL ACT WITHOUT A THOROUGH ANALYSIS OF THE ACT'S LANGUAGE, PURPOSE AND LEGISLATIVE HISTORY.

In *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992), this Court ruled that the Public Health Cigarette Smoking Act of 1969 preempted certain state tort claims. The ruling was based on this Court's interpretation of section 5(b) of that Act, which states that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the package of which are labeled in conformity with the provisions of this Act." 15 U.S.C. § 1334(b). Despite the fact that the Act does not mention common law and despite this Court's finding that the Act's predecessor statute, the Federal Cigarette Labeling and Advertising Act of 1965, preempted only "positive enactments by legislatures or administrative agencies", 112 S. Ct. at 2618-19, this Court held that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words can easily encompass obligations that take the form of common law rules." 112 S. Ct. at 2620.

This Court found that the difference between the two Acts was in the change in terminology from the 1965 Act to the 1969 Act. The 1965 Act expressly preempted federal, state and local rulemaking bodies from requiring "any statement" that conflicted with mandated warning labels, but the 1969 Act changed that to bar any "requirement or prohibition" imposed under state law. Another change that convinced this Court that the 1969 Act had a broader effect than the 1965 Act was that the 1969 Act extends beyond

statements in advertising to include obligations "with respect to advertising or promotion" of cigarettes.

After holding that the 1969 Act preempted state tort claims, this Court narrowed the preemption by specifying which tort claims were preempted and which were not. Reiterating the view that the preemption section must be narrowly construed, this Court concluded that claims of failure to warn (insofar as they rest upon the proposition that the defendants should have included additional or more clearly worded warnings) and fraudulent misrepresentation (insofar as they rest upon the defendant's false advertising to neutralize the effects of the federally mandated warning labels), were preempted, but that claims based on breach of express warranty, fraudulent misrepresentation (insofar as they concealed material facts in violation of a state law duty to disclose such facts), and intentional conspiracies to misrepresent or conceal material facts concerning the health hazards of smoking were not preempted.

This Court analyzed the language, purpose and legislative history of the Public Health Cigarette Smoking Act of 1969 and its predecessor, the Federal Cigarette Labeling and Advertising Act of 1965, before reaching the conclusion that common law tort claims were preempted by the Act. In the case at bar, the United States District Court for the District of New Jersey and the United States Court of Appeals for the Third Circuit applied this Court's ruling in *Cipollone* to the Medical Device Amendments Act of 1976 (MDA) without making any such analysis, holding that because the MDA uses the term "requirement" in its preemption clause, the Act preempts all state law tort claims. [*Gile v. Optical Radiation Corporation*, slip op. at 8a]

Since the *Cipollone* decision, several other courts have come to the same conclusion and have held that the MDA expressly preempts state tort law claims. See *Hinners v. Optical Radiation*

Corp., 15 F.3d 1096 (11th Cir. 1994) (per curiam); *Duncan v. IOLAB Corp.*, 12 F.3d 194 (11th Cir. 1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130 (lst Cir. 1993), *cert. denied*, 114 S. Ct. 84 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), *cert denied*, 113 S. Ct. 327 (1992); *Moore v. Kimberly-Clark*, 867 F.2d 243 (5th Cir. 1989), *rehearing denied*, 873 F.2d 297 (1989); *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D. Pa. 1992); *Covey v. Surgidev Corp.*, 815 F. Supp. 1089 (N.D. Ohio 1993). These courts have misinterpreted the language of the MDA and have extended the rationale in *Cipollone* far beyond what this Court intended in its limited ruling, and it is respectfully submitted that this Court settle the matter by reviewing the decision in *Gile v. Optical Radiation Corporation.*

From the beginning of our constitutional history, the right to seek redress has been recognized as fundamental because "the very essence of civil liberty is the right of every individual to claim the protection of the laws whenever he receives an injury" and because "[o]ne of the first duties of government is to afford that protection." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). This right, recognized at common law, is essential to the orderly pursuit of happiness by free people. *Ingraham v. Wright*, 430 U.S. 651 674 (1977). The preservation of common law tort actions is vital to compensate injured victims and to encourage safety. *See, e.g., Buzzard v. Roadrunner Trucking*, 966 F.2d 377 (3d Cir. 1992) (adherence to a federal safety standard regarding lighting and reflective devices did not preempt common law.) The principle that federal preemption is to be narrowly and sparingly applied has recently been reaffirmed by the United State Supreme Court in *GSX Transportation v. Easterwood*, 112 S. Ct. 1732 (1993).

The Bill of Rights of the United States Constitution protects the common law rights of our citizens. The First Amendment states

that "Congress shall make no law . . . abridging the right of the people to petition the Government for redress of grievances." The Seventh Amendment states that "in suits at common law, the right to trial by jury shall be preserved." And the Tenth Amendment states that powers not delegated to the United States by Constitution, nor prohibited by it to the States, are reserved to the States respectively for the people. Furthermore, the common law preceded the Constitution. Consequently, any attempt to take away an individual's fundamental right of access to the courts to seek redress raises serious constitutional questions and is subject to the strictest scrutiny.

An analysis of whether federal law preempts state common law must begin with the "basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). It is a well settled principle that "the historic police powers of the state" are not to be superseded by a federal act unless that is the "clear and manifest purpose of Congress." *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. at 2617, quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). The presumption against preemption of state law is even stronger and is almost conclusive when it interferes with the traditional right of the states to protect the health and safety of their citizens through common law tort liability, and no alternate remedies or forum are provided. *Hillsborough County v. Automated Medical Labs*, 471 U.S. 707 (1985); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947); *Abbot by Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988), *cert. denied*, 488 U.S. 908 (1988). As stated in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984), "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."

But this is exactly what the courts in the case at bar have done. They have left Mrs. Gile and the thousands of other elderly citizens who participated in this medical experiment without a means of

judicial recourse for their injuries. The courts have done this based on their interpretation of a single word, a result that clearly was not intended either by Congress when it passed the Medical Device Amendments of 1976 or by this Court when it interpreted the word with respect to the Public Health Cigarette Smoking Act.

Standard techniques of statutory interpretation require reference to the structure of the statute and its legislative history. *Chevron U.S.A. v. Natural Resources Defense Council,* 467 U.S. 837 (1984); *National R.R. Passenger Corp. v. Boston & Maine Corp.*, 112 S. Ct. 1394 (1992). In the case at bar, reference to the language of the Medical Device Amendments of 1976, its legislative history, its implementing regulations, and the language of the Food, Drug and Cosmetic Act and its regulations, establishes that the MDA does not preempt state common law claims.

A. The Language of the Medical Device Amendments.

There is no language in the MDA indicating that state common law tort claims are either preempted or not preempted. In *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989), the court found that state tort claims were not preempted by the MDA in part because the plain language of section 360k indicates that Congress intended to preempt only state or local legislation and administrative regulations. The court noted that the common law is never mentioned in the MDA and that there is no provision of a federal remedy for persons injured by medical devices.

Section 521 of the MDA contains an express provision governing preemption. This section provides:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —

> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). The word "requirement" is mentioned three times in this subsection, but only once does it appear to be ambiguous. In sections 360k(a)(1) and 360k(a)(2), the phrases "any requirement applicable under this Act to the device" and "a requirement applicable to the device under this Act" can refer only to positive enactments such as legislation and cannot refer to common law tort claims since the FDA has no authority under the MDA to impose requirements through common law tort actions. While Congress could have intended that the first mention of the word "requirement" in section 360k(a) would have a different meaning than the next two uses of the term, it is highly unlikely that Congress would adopt two separate meanings of a word within one section of a statute.

The use of the term "requirement" in the next subsection of section 360k also shows that Congress did not intend this term to include the common law. Section 360k(b) provides for exemptions from preemption:

> (b) Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision

> applicable to a device intended for human use if—
>
> > (1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
> >
> > (2) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

There is no way that a State or political subdivision can petition the FDA for an exemption for each and every verdict given in common law tort suits. Consequently, this subsection clearly shows that there was no intent to have the term "requirement" include the common law.

Other sections of the MDA indicate that there is an intent not to preempt state common law claims. For instance, 21 U.S.C. § 360h(d), dealing with FDA orders requiring producers and distributors to repair, replace or provide refunds with respect to defective devices, provides that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law." The section also provides that "[i]n awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy, provided him under such order shall be taken into account."

21 U.S.C. § 360pp(e) provides that "compliance with this part of any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law." 21 U.S.C.

§ 360pp(f) provides that "the remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law." 21 U.S.C. § 360g(e), governing judicial review, provides that "remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law."

Clearly, the plain language of the MDA shows that Congress intended that remedies other than those in the MDA itself were to remain available to injured persons.

B. The Legislative History of the Medical Device Amendments.

There is no mention in the legislative history of the MDA of an intent that state common law claims be preempted. Nor is there any mention of an intent to insulate manufacturers from common law liability. The purpose of the MDA is to protect the public from dangerous devices. In introducing the MDA, Senator Edward Kennedy stated that

> the legislation was written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunction. . . . Full judicial review has been built into every step of the [MDA].

121 Cong. Rec. 10688-89 (Daily Ed., April 7, 1975). Senator Kennedy also stated that in the context of the then-recent Dalkon Shield disaster, it was the intent of the MDA to require the same standards of safety and effectiveness as those for prescription drugs. *Id.* at 10688. Clearly, the common law applied to the standards of safety and effectiveness for prescription drugs.

The MDA is part of the Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. §§ 301-392. The original FDCA contained a

provision specifically preserving a right of action for damages, but the provision was stricken as unnecessary legislation because "a common law right of action [already] exists." See H.R. 6110, 73d Cong., 1st Sess. Section 25 (1933) and *Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 1944*, 73d Cong., 2d Sess. 400, 403 (1933). It is ludicrous to imagine that the Congress intended that the FDCA as a whole does not preempt common law rights of action but that one small part of the FDCA does preempt common law rights of action. Furthermore, it is unlikely that the Congress would wipe out the common law without comment and without providing a remedy for consumers injured by unsafe medical devices.

C. The Safe Medical Device Act.

In 1990, Congress enacted the Safe Medical Device Act (SMDA), which amended the MDA to resolve some problems and to improve the MDA. H.R. Rep. No. 101-808, 101st Cong., 2d Sess. 8 (1990), reprinted in 1990 U.S.C.C.A.A.N. §§ 6305-6307. The SMDA made no changes to the express preemption provision in the MDA. When Congress amends a statute, it is presumed to know the law in effect at the time. *United States v. Austin*, 614 F. Supp. 1208 (D.N.M. 1985). In 1990, the prevailing law was that section 360k did not expressly preempt common law. *Callan v. G.D. Searle & Co., supra; Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988). Consequently, the failure to change § 360k to provide for express preemption indicates that it was the intent of Congress to adopt the prevailing construction of the statute — that the common law was not preempted.

D. The Consumer Product Safety Commission Improvements Act of 1976 and Its Relationship to the MDA.

At the same time that Congress was drafting the MDA, it was also drafting the Consumer Product Safety Commission Improvements Act of 1976, which amended the Consumer

Products Safety Act, 15 U.S.C. §§ 2051-2083, the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-2376, the Flammable Fabrics Act, 15 U.S.C. §§ 1191-1204, and the Poison Prevention Packaging Act, 15 U.S.C. §§ 1471-1474. In drafting the MDA, Congress borrowed the preemption provisions from these acts, specifically, provisions providing procedures for states to petition for exemption from preemption. The purposes of the CPSC Acts and the MDA are the same — to protect the public from dangerous consumer products. Because the CPSC acts and the MDA were drafted virtually simultaneously and adopt similar approaches to preemption, established principles of statutory construction suggest that these two statutes be read consistently. See *Hague v. Committee for Industrial Organization*, 307 U.S. 496, 59 S. Ct. 954, 83 L. Ed. 1423 (1939). Congress did not mention preemption of common law tort claims as one of its purposes in enacting preemption clauses in the CPSC acts. To the contrary, Congress amended the preemption section in the Consumer Product Safety Act without modifying that act's savings clause, which provides that "[c]ompliance with consumer product safety rules or other rules or orders under this Act shall not relieve any person from liability at common law or under State statutory law to any other person." 15 U.S.C. § 2073(a). Furthermore, in addressing preemption, Congress used the terms "requirements" and "standards" interchangeably. *See* S. Rep. No. 94-251, 94th Cong., 1st Sess. 4 (1975); H. Rep. No. 94-325, 94th Cong. 1st Sess. 10 (1975); H. Rep. No. 94-1022, 94th Cong., 2d Sess. 29 (1976). Clearly, the implication is that Congress did not intend that the term "requirement" be interpreted more broadly than the term "standard" with respect to acts enforced by the Consumer Product Safety Commission.

The Federal Hazardous Substances Act (FHSA) uses the term "requirement" in a similar manner to the use of the term in the MDA. The preemption provision of the MDA provides that if under regulations promulgated by the Commission, "a

requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations." 15 U.S.C. § 1261. There is no indication that Congress intended to preempt common law tort claims under the FHSA while preserving them under the other acts enforced by the CPSC. To the contrary, in the report of the Senate Commerce Committee, it was stated that the legislation "would provide a uniform Federal preemption clause for the Federal Hazardous Substances Act, the Flammable Fabrics Act, and the Consumer Product Safety Act." S. Rep. No. 94-251, 94th Cong., 1st Sess. 4 (1975).

The clear implication is that Congress did not intend to preempt common law tort claims when it added preemption provisions to the CPSC acts or the MDA.

E. Summary

To summarize, there is no clear statement of intent to preempt state common law tort claims in the Medical Device Amendments of 1976. Without a clear statement of intent by the Congress, federal law cannot be found to preempt state common law. The plain language of the MDA indicates that the use of the term "requirement" in the preemption provision of the MDA is limited to positive enactments of a legislative nature, not to common law tort claims. The legislative history establishes that the Food, Drug and Cosmetic Act, of which the MDA is a small part, does not preempt common law tort claims. When it amended the MDA with the Safe Medical Device Act, Congress did not amend the preemption provisions even though the prevailing law was that state common law tort claims were not preempted. Reading the MDA in *pari materia* with the Consumer Product Safety Acts, which were amended at the same time the MDA was drafted,

shows that there was no intent to preempt common law tort claims in either the MDA or any of the CPSC acts.

The courts below took this Court's conclusion in *Cipollone* that the term "requirement" in the Public Health Cigarette Smoking Act of 1969 preempts common law tort claims and applied it to another federal statute without analyzing the language of the statute, the purpose of the statute, and the legislative history of the statute, and without using standard techniques of statutory construction. By doing so, they have gone beyond the intention of this Court's narrow ruling in *Cipollone* and they have impermissibly taken away the plaintiff's fundamental right of access to the courts to seek redress. Their interpretation of section 360k(a) of the MDA, which takes away a forum from injured victims and does not provide an alternate forum, cannot pass the strictest scrutiny that is required to take away the fundamental right of access to our courts. Consequently, the interpretation is unconstitutional. There can be no doubt that courts must refrain from creating, by interpretation, an unconstitutional or questionably constitutional position. *International Ass'n. of Machinists v. Street*, 367 U.S. 740, 749 (1961).

Under the circumstances, it is respectfully requested that this Court review the decision of the Third Circuit in *Gile v. Optical Radiation Corporation.*

II.

THE MEDICAL DEVICE AMENDMENTS OF 1976 AND THE FDA REGULATIONS EXPRESSLY PROVIDE FOR THE EXEMPTION FROM PREEMPTION OF CERTAIN CLAIMS; THEREFORE, NOT ALL OF PLAINTIFF'S CLAIMS ARE PREEMPTED.

In affirming the summary judgment granted by the District Court, the Third Circuit held that all of Mrs. Giles' tort claims were preempted by the MDA. But even assuming arguendo that the MDA expressly preempts state common law tort claims, under the plain language of the MDA and its implementing regulations as well as the interpretation of the exemptions to preemption made by the court in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), some of Mrs. Giles' tort claims are exempt from preemption. Even in *Cipollone,* this Court did not apply a blanket preemption but specified those claims that were preempted and those that were not preempted. Consequently, it is respectfully submitted that a review of the instant decision is appropriate in order for this Court to settle the matter.

The Medical Device Amendments of 1976 (MDA) and its implementing FDA regulations do not require preemption of all claims from injured persons. They specifically provide for the exemption from preemption of the following: (1) requirements of general application where the purpose of the requirement relates to other products in addition to devices, (2) requirements prohibiting the manufacture of adulterated or misbranded products, and (3) requirements regarding informed consent.

A. Any Express Preemption Is Not A Blanket Preemption.

Even assuming arguendo that there is an express preemption of state common law claims in the MDA, it is not a blanket preemption. In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330,

1334 (7th Cir. 1992), the court stated that the preemption found in the MDA "is not the sort of blanket preemption that we find in ERISA, which supersedes 'any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.' " The *Slater* court stated that with regard to intraocular lens implants, the scope of the preemption in the MDA "is limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety or efficacy of the experimental lenses." *Id.*

There are specific provisions in the MDA, the FDA regulations implementing the MDA and the Investigational Device Exemptions (IDE) that exempt certain claims from preemption. These include claims falling under requirements of general application, claims of adulterated products and claims of failure to obtain informed consent.

B. Claims Under the UCC are Exempted from Preemption.

In 21 C.F.R. § 808.1(d)(1), it is declared that other state and local requirements that affect devices are not preempted by section 521(a) because they are not "requirements applicable to a device" within the meaning of the act. One of the examples given of state or local requirements that are not preempted by section 521(a) is

> State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

One of Mrs. Gile's claims is that the lens was not fit for its intended purpose. This claim is clearly encompassed in the Uniform

Commercial Code and is therefore exempted from preemption. Mrs. Gile also claims that the respondent breached its warranty of merchantability, another claim encompassed by the Uniform Commercial Code and therefore also exempted from preemption. Even assuming that these claims have been subsumed into New Jersey's Products Liability Act, N.J.S.A. § 2A:58C-2, they would still be exempt from preemption under this section. New Jersey's Product Liability Act clearly relates to other products in addition to devices.

The argument that the Uniform Commercial Code or the Products Liability Act are concerned with the safety and effectiveness of a product is irrelevant here, since the FDA obviously took that into consideration in providing exemptions from section 521(a) for such laws.

C. Claims of Adulterated Products Are Exempted from Preemption.

The FDA has also provided for an exemption from preemption for any state or local requirement prohibiting the manufacture of adulterated or misbranded products. 21 C.F.R. § 808.1(d)(6)(ii). In the case at bar, it is Mrs. Gile's contention that the intraocular lens was adulterated because the respondent disregarded the FDA regulations in manufacturing it. Consequently, this claim is not preempted.

D. Claims of Failure to Obtain Informed Consent Are Exempt from Preemption.

Mrs. Gile's claim that respondent failed to warn her of the risks by failing to obtain an informed consent is also exempt from preemption. The IDE for Intraocular Lenses requires that informed consent be obtained from subjects of the investigation. 21 C.F.R. § 813.25(a)(11). The FDA regulation regarding Informed Consent of Human Subjects, 21 C.F.R. § 50.25(c), provides:

> The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State or local laws which require additional information to be disclosed for informed consent to be legally effective.

In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992), the court stated that the preemption in the MDA does not affect cases charging failure to obtain the patient's informed consent to the implantation of the lens. The court went on to note that the limited scope of the preemption explains the prohibition against the inclusion of "any exculpatory language" in informed consent forms which is incorporated by reference in the IDE for intraocular lenses. The court stated that this prohibition "preserves the patient's common law rights outside of the limited scope of the preemption provision."

This clearly means that the patient's common law right to recover for a defendant's failure to obtain an informed consent is preserved, since the scope of the preemption is limited to sanctions imposed for *compliance* with federal regulations. A defendant does not comply with the federal regulations if it does not obtain informed consent. To the extent that *Hunsaker v. Surgidev Corporation*, 818 F. Supp. 744 (M.D. Pa. 1992), rules otherwise, it is incorrect.

Informed consent to the implantation of an investigational intraocular lens is not obtained unless the patient is fully informed of all of the risks, including the risk that her common law right to recover for injuries caused by the lens itself will be lost. The court in *Slater* stated that even within the scope of the preemption there is an important qualification in that the risks of the experimental procedure must be adequately explained to the patient, and must include the risk of loss of tort remedies. *Id.* The informed consent form signed by Mrs. Gile, included in the appendix at 42a, does not

contain an explanation that she is giving up her right to file a tort claim against Optical Radiation Corporation. Clearly, it was not adequately explained to Mrs. Gile that she would have no right to file a tort claim if the lens caused an injury to her. Therefore, this claim is not preempted.

Furthermore, all of the risks of the experimental procedure must be adequately explained to the patient, since the tort of medical battery, which is violated when an operation is performed without the patient's informed consent, is not preempted by section 521(a). *Slater v. Optical Radiation Corp., supra.* In the case at bar, all of the risks were not adequately explained to Mrs. Gile. Respondent Optical Radiation Corporation knew or should have known that the intraocular lenses themselves were not fit and could cause serious damage to a patient's eyes. The informed consent form signed by Mrs. Gile does not contain this warning. It refers only to complications caused by lens *implantation,* not to complications caused by the lens itself. It does not explain that the lens itself may not be fit for implantation into the eye and that the lens itself may cause serious damage and may result in the loss of vision in the eye.

The actual informed consent form signed by Mrs. Gile was not provided by Optical Radiation Corporation. It was a form provided by IOLAB, one of the respondent's competitors. The Third Circuit stated that a claim for informed consent addresses the duty of the physician, not the manufacturer, to the patient. [Slip op. at 9a] However, this ignores the express provision of 21 C.F.R. § 813.46(c), which provides that it is the sponsor's responsibility to ensure that the investigator complies with the requirements for informed consent. Clearly, since the respondent did not even ensure that the investigator used the respondent's own informed consent form, the respondent failed to comply with the federal regulations. It was the respondent's responsibility to ensure that the treating physician obtain informed consent from the patient

before implanting the respondent's lens into the patient's eyes. Informed consent is obtained not only by a patient reading a form but also by the physician adequately explaining all of the risks to the patient. *Largey v. Rothman,* 110 N.J. 204 (1988). It must be remembered that in the case at bar, Mrs. Gile was suffering from cataracts and that reading a form was probably difficult for her. Clearly, respondent Optical Radiation Corporation did not ensure that its investigators obtained informed consent from the patients.

Without knowing all of the risks involved in the implantation of the intraocular lens, included the risk of giving up her right to sue for injuries, Mrs. Gile did not give her informed consent to the operation. Respondent Optical Radiation Corporation failed to obtain Mrs. Gile's informed consent and failed to comply with the FDA regulations. Consequently, this claim is not preempted.

E. Claims of Fraudulent Misrepresentation Are Exempt from Preemption.

In addition to these express exemptions from preemption, plaintiff's claim of fraudulent misrepresentation is also exempt from preemption. In *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992), the United States Supreme Court held that allegations of intentional fraud and misrepresentation by false representation of a material fact and by concealment of a material fact are not preempted since they rely on a state law duty to disclose such facts. The Court noted that state law proscriptions on intentional fraud rely only on a single, uniform standard: falsity. Since Mrs. Gile's claims that respondent fraudulently misrepresented the quality of the lens and withheld information concerning the risks and hazards of the lens are based on the general duty not to make fraudulent statements, her claims are not preempted.

F. Summary

It is clear that even assuming that the MDA preempts state common law, not all of Mrs. Gile's claims are preempted by federal law. Any express preemption in the MDA is not a blanket preemption and certain specific claims are exempt from preemption. In particular, Mrs. Gile's claim that the lens was not fit for its intended purpose is exempt from preemption because the claim falls under a state law of general application which has been expressly exempted from preemption in 21 C.F.R. § 808.1(d)(1). Mrs. Gile's claim that the lens was adulterated has been expressly exempted from preemption in 21 C.F.R. § 808.1(d)(6)(ii). Mrs. Gile's claim that her informed consent was not obtained is expressly exempted from preemption in 21 C.F.R. § 50.25(c) and the interpretation of the failure to obtain informed consent given by the court in *Slater, supra.* In addition, Mrs. Gile's claims of fraudulent misrepresentation are exempt from preemption under the interpretation of this cause of action given by the United States Supreme Court in *Cipollone, supra.*

CONCLUSION

For these reasons the Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit should be granted.

Respectfully submitted,

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August 1, 1994

APPENDIX A —JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT DATED MAY 3, 1994

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 93-5555

HELEN GILE,

Appellant

v.

OPTICAL RADIATION CORPORATION; XYZ COMPANIES, #1 through #5; JOHN DOES, #1 through #5

Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 92-02957)

Present: HUTCHINSON, ROTH and ROSENN, *Circuit Judges*

JUDGMENT

This cause came to be heard on the record from the United States District Court for the District of New Jersey and was argued by counsel March 24, 1994.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court entered August 25, 1993, be, and the same is hereby affirmed. Costs Taxed against appellant.

Appendix A

ATTEST:

s/ P. Douglas Sisk
CLERK

Dated: May 3, 1994

Certified as a true copy and issued in lieu
of a formal mandate on May 25, 1994.
Teste: s/ P. Douglas Sisk
Clerk, U.S. Court of Appeals for the Third Circuit.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT FILED MAY 3, 1994

Filed May 3, 1994

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 93-5555

HELEN GILE,
Appellant

v.

OPTICAL RADIATION CORPORATION; XYZ COMPANIES, #1 through #5; JOHN DOES, #1 through #5

Appeal from the United States District Court
for the District of New Jersey
D.C. No. 92-cv-02957

Argued March 24, 1994

Before: HUTCHINSON, ROTH, and ROSENN, *Circuit Judges*

Opinion Filed May 3, 1994

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Appendix B

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OPINION OF THE COURT

ROSENN, *Circuit Judge.*

This case raises an interesting question of liability which has its origin in the coordinated efforts of the Government and manufacturers of optical medical devices to advance the cause of medical treatment through research, experimentation, and optimum freedom for scientific investigation in the pursuit of that purpose.

In 1981, the Food and Drug Administration (FDA) approved for clinical investigation an intraocular lens manufactured by defendant Optical Radiation Corporation (ORC). An intraocular lens (IOL) is a lens intended to replace surgically the natural lens of the human eye. In December 1985, Dr. Henry Scimeca, an investigator approved by the FDA, implanted in the eye of plaintiff Helen Gile, who suffered from cataracts, an ORC model UV11H intraocular lens. Prior to the surgery, Gile signed an informed consent form, which she claims that she did not read before signing. Gile subsequently had the ORC lens surgically removed from her left eye, and is now legally blind in that eye.

In May of 1992, Gile commenced this products liability and negligence action against ORC in the Superior Court of New Jersey. ORC removed the case to the United States

District Court for the District of New Jersey.[1] Thereafter, ORC moved for summary judgment on the ground that Gile's claims were expressly preempted under the Federal Food, Drug and Cosmetic Act (FDCA or the Act), 21 U.S.C. § 301 *et seq.* The district court entered summary judgment in favor of ORC and dismissed the complaint with prejudice. Gile timely appealed to this court. We affirm.

I.

This court exercises plenary review over a grant of summary judgment, and we apply the same test the district court should have utilized initially. *Oritani Sav. and Loan Ass'n v. Fidelity and Deposit Co.*, 989 F.2d 635, 637 (3d Cir. 1993). Summary judgment is appropriate only when it is demonstrated that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-32 (1986); Fed.R.Civ.P. 56(c). An issue of material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In deciding a motion for summary judgment, all reasonable inferences must be drawn in favor of the non-movant. *Oritani*, 989 F.2d at 638.

At the heart of this action are the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, to the FDCA. Pursuant to the FDCA, and amendments thereto, including the MDA, the FDA strictly regulates the development, marketing, and monitoring of medical devices. The MDA sets forth various requirements concerning the safety and effectiveness of medical devices and the approvals to be obtained from the FDA before bringing a device to the market. The MDA also limits entities other

1. The district court exercised diversity jurisdiction over this case pursuant to 28 U.S.C. § 1332. This court has jurisdiction over this appeal from a final order pursuant to 28 U.S.C. § 1291.

than the FDA from imposing requirements on the makers o medical devices and the process by which those devices ar discovered, investigated, and manufactured. Sectio 360k(a), the focus of this appeal, provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In enacting the MDA, Congress recognized the need for special treatment of investigational devices which, by their very nature, could not meet the requirements applicable to marketed devices:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Persons seeking an exemption from pre-market approval for a particular medical device (an "investigational device exemption" or "IDE") must apply to the FDA for permission to undertake clinical investigations. *Id.* at § 360j(g)(2)(A).

The FDA issued specific regulations governing the development of IOLs. 21 C.F.R. § 813 *et seq.* (the "IOL Regulations"). The regulations require a detailed application, describing the device under investigation and

setting forth a plan for studying its use in human subjects, which is reviewed by both the FDA and an institutional review committee. 21 C.F.R. §§ 813.20, 813.30. The device must be described in sufficient detail to permit "a knowledgeable judgment about the anticipated safety and effectiveness of the lens." *Id.* at § 813.20(b)(2). After approval, the committee has a duty to monitor the clinical investigation. *Id.* at § 813.65. The regulations detail the monitoring of the studies and set forth reporting and recordkeeping requirements, including evaluation of complaints about devices. *Id.* at §§ 813.46, 813.180 *et seq.* Under the IOL Regulations, the FDA can refuse an exemption if it finds, *inter alia*, that the lens may be unsafe or ineffective, that the investigational plan is not a reasonable one, or that manufacturing, storage, and implantation methods do not assure adequate safety and effectiveness. 21 C.F.R. § 813.30(c). In sum, the IOL Regulations broadly govern nearly all facets of the investigational program. *See Covey v. Surgidev Corp.*, 815 F. Supp. 1089, 1095 (N.D.Ohio 1993) ("[t]o say that the regulations covering intraocular lenses are expansive would be an understatement").

II.

Gile first argues that Congress never intended to preempt state common law when it passed the MDA. She contends that the word "requirement" in 21 U.S.C. § 360k(a) refers only to positive legislative enactments and not to state tort common law claims. This argument must be rejected, however, in light of *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The *Cipollone* Court addressed the Public Health Cigarette Smoking Act of 1969, which preempted certain "requirement[s] or prohibition[s] ... imposed under state law." The Court rejected the contention that the act did not extend to state tort claims:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive

> enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."
>
> Although portions of the legislative history of the 1969 Act suggest that Congress was primarily concerned with positive enactments by States and localities, the language of the Act plainly reaches beyond such enactments.

112 S.Ct. at 2620; 120 L.Ed.2d at 426 (citations and footnote omitted). Thus, the Supreme Court has clearly stated that the word "requirement," in the context of an express preemption provision, includes state law claims. *See also Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1133 (1st Cir. 1993), *cert. denied*, 114 S. Ct. 84 (1993).

Gile contends that there cannot be express preemption unless Congress uses "the words 'common law' or something analogous" to indicate its intent to preempt such claims. However, the MDA, providing "no State or political subdivision of a State may establish ... any requirement ... different from, or in addition to, any requirement applicable under this chapter," is indistinguishable from the act at issue in *Cipollone*, which provided, "[n]o requirement or prohibition ... shall be imposed under State law with respect to the advertising ... of any cigarettes." Thus, Gile's argument that Congress needs to explicitly provide that common law claims are preempted in order to find express preemption is unpersuasive.

Gile further argues that even if her tort claims in general are preempted under § 360k, her specific claims based on lack of informed consent and adulterated products are

exempt from preemption. First, she relies on 21 C.F.R. §§ 50.20 and 50.25(c) as support for her contention that her claim for failure to obtain informed consent is not preempted. Section 50.20, which addresses general requirements for informed consent, provides in part: "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." Section 50.25(c), which addresses elements of informed consent, provides: "[t]he informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective." Gile further notes that the court in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), *cert. denied*, 113 S.Ct. 327 (1992), held that not all claims are preempted under § 360k, including claims for informed consent. *Id.* at 1334.

The *Slater* court, however, stated that 21 C.F.R. § 50.20 "preserves the patient's common law rights outside of the limited scope of the preemption provision. It does not . . . repeal the preemption provision itself." *Id.* Similarly, the court in *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D.Pa. 1992) concluded that "the consent regulation should be read to prevent patients from waiving legal rights *which are not preempted under federal law.* That is, those common law rights which are retained by a patient and not preempted by the federal scheme may not be waived by the patient." *Id.* at 750 (emphasis in original). Gile, however, ignores that the predicate of a claim for informed consent addresses the duty of the physician, not the manufacturer, to the patient. *See e.g., Largey v. Rothman*, 540 A.2d 504 (N.J. 1988); *Kershaw v. Reichert*, 445 N.W.2d 16 (N.D. 1989). She is unable to provide any support for her contention that she is entitled to bring such a claim against the manufacturer of an experimental product. Moreover,

despite the completion of discovery in this action, Gile has not offered any proof to support her vague allegation that ORC failed to provide her physician with the proper forms and information necessary to obtain informed consent.

Gile next quotes the first sentence of section 808.1(d)(6)(ii) of the FDA Regulations, which states: "[g]enerally, [§ 360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices." 21 C.F.R. § 808.1(d)(6)(ii).[2] But the next sentence, not quoted by Gile, provides:

> Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.

Id. This action by Gile challenging the design of the Stableflex lens and the warnings and instructions that accompanied it, if successful, would impermissibly result in new common law standards for lens design and warnings. *See e.g., Stamps*, 984 F.2d at 1421-22; *King*, 983 F.2d at 1135-36; *Slater*, 961 F.2d at 1333. Thus, it is preempted. Moreover, read in its entirety, section 808.1 prohibits, not supports, challenges such as Gile's to FDA requirements affecting the safety and effectiveness of investigational devices under the guise of product liability actions by reflecting the FDA's determination that the word "requirement," as used in § 360k, includes "court decisions."[3]

---

2. 21 C.F.R. § 808.1(d) sets forth examples of state or local requirements that are not preempted by § 360k. Significantly, the list of requirements exempted from § 360k *does not include state tort or common law claims.*

3. Section 808.1(b) states:

> [Section 360k provides that] no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force

(Cont'd)

Similarly, Gile's argument that her claims are not preempted because the IOL was "adulterated" within the meaning of 21 U.S.C. § 351(i) must fail.[4] The FDA can determine an investigational device to be adulterated if requirements under the IDE are not complied with. Here, the FDA made no findings of adulteration and the record does not contain any facts to support such a claim. Moreover, violations of the FDCA do not create private rights of action. *See e.g., Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1022 (E.D.Mich. 1993); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33, 35 (M.D.Pa.), *aff'd*, 902 F.2d 1558 (3d Cir. 1989). Thus, only the government has a right to take action with respect to adulterated products. Additionally, as noted by the district court, to the extent Gile's adulteration claim is derivative of her other claims for inadequate design, manufacture, and warnings, she cannot overcome a finding of preemption merely by claiming that the product was adulterated.

(Cont'd)

and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b) (emphasis added). *See Stamps*, 984 F.2d at 1421 n.1.; *King*, 983 F.2d at 1134; *Slater*, 961 F.2d at 1331.

4. 21 U.S.C. § 351(i) provides that a device shall be deemed to be adulterated "[i]f it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section."

Appendix B

III.

Every court that has considered the issue of the preemptive effect of § 360k in the context of ORC's product, has ruled in favor of ORC. *See Slater*, 961 F.2d 1330; *Hinners v. Optical Radiation Corp.*, 15 F.3d 1096 (11th Cir. 1994) (per curiam); *Rogers v. Optical Radiation Corp.*, 12 F.3d 194 (11th Cir. 1994). In *Slater*, as here, the plaintiff alleged that following implantation of a Stableflex lens, his vision deteriorated and the implant had to be removed, leaving him with permanent damage. 961 F.2d at 1332. The plaintiff in *Slater* advanced causes of actions for strict liability, breach of warranty, failure to provide adequate warnings, negligent design, and failure to conduct proper clinical testing. *Slater v. Optical Radiation Corp.*, 756 F. Supp. 370, 371-72 (N.D. Ill. 1991), *aff'd*, 961 F.2d 1330 (7th Cir. 1992). The lens in *Slater*, like the one in this case, was governed by the IOL Regulations. 961 F.2d at 1331.

The district court in *Slater* found that all of the plaintiff's claims were expressly preempted by § 360k, and granted the defendant's motion to dismiss the entire complaint. The Seventh Circuit affirmed, emphasizing that § 360k(a) forbids states to subject a medical device to requirements "different from, or in addition to" requirements that relate to the safety and effectiveness of the device. The *Slater* court noted that although the regulations imposed no requirement concerning the specific design of intraocular lenses,

> [t]he FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective.

961 F.2d at 1333 (citation omitted). The court concluded:

> The theory underlying the complaint is that the design of the Stableflex was not sufficiently safe and effective

> to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that the Stableflex could be sold, subject only to requirements, procedural in character and, so far as appears, fully complied with, designed to assure that this experimental distribution was in fact a worthwhile experiment. The plaintiff wishes in the name of state tort law to impose additional requirements—namely that the Stableflex have had design characteristics that it lacked—and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments.

Id.

Gile argues that *Slater* is not persuasive because the court noted that preemption "is limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety or efficacy of the experimental lenses." 961 F.2d at 1334. Gile submits that she is not seeking to impose sanctions for compliance with regulations, but rather is seeking damages for injury received and for the failure to warn of the danger of the experiment. The quoted dicta from *Slater*, however, preceded the court's observation that preemption under § 360k would not affect claims based on negligence in the implantation of a lens, negligence in the removal of a lens, contamination of the lens by bacteria or fungi, or medical battery resulting from failure to obtain the patient's informed consent to the procedure. *Id.*

Notably, all of these claims might be brought against a physician, not against the lens manufacturer. The dicta does not detract from *Slater*'s holding that the plaintiff's claims for negligence, strict liability, and breach of warranty against the manufacturer were preempted under § 360k as impermissible attempts to impose additional safety and

effectiveness requirements on the manufacturer. *See also Rogers*, 12 F.3d 194 (11th Cir. 1994) (affirming entry of summary judgment in favor of ORC on plaintiff's causes of action for design defect, inadequate warning, breach of warranty, and inadequate testing on express preemption grounds); *Hinners*, 15 F.3d 1096 (11th Cir. 1994) (affirming dismissal of plaintiff's claims regarding safety and effectiveness of intraocular lenses on preemption grounds).

In the only IOL case within this circuit, *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744 (M.D.Pa. 1992), the court agreed with *Slater* that "the standards implicit in the state tort actions would be 'different from or in addition to' those requirements of both the FDCA and the IDE regulations." *Id.* at 752 (citation omitted). The court reasoned that the difference between experimental devices and those approved for marketing supports a finding of express preemption under § 360k. *Id.* at 749. The court concluded:

> A jury determination that the device is not sufficiently safe and effective would not only be contrary to the experimental purposes of the exemption, but, more important, would directly conflict with the FDA's contrasting judgment. Therefore, state tort law invoked to challenge the safety or effectiveness of a IOL which is part of an FDA investigation is federally preempted.

Id. at 752-53. Thus, the district court's finding of preemption under § 360k is in conformance with the holdings of the vast majority of cases which have addressed this issue.[5]

---

5. In light of our statutory interpretation and the extensive authority discussed above, we reject Gile's sole reliance on two lower court cases from Louisiana, *Lewis v. Intermedics Intraocular*, No. 93-0007 (E.D.La. Dec. 9, 1993) and *Mitchell v. IOLAB Corp.*, 700 F. Supp. 877 (E.D. La. 1988).

IV.

Next, Gile argues that public policy favors remedies for victims of medical experimentation. Gile erroneously contends that if preemption is permitted, medical device manufacturers will be granted immunity for all manner of improper acts. As explained by ORC, violations of the FDCA and FDA regulations are punishable by significant fines, civil penalties, and imprisonment. Similarly, Gile's assertion that preemption will encourage shoddy clinical investigations and development of defective medical devices lacks merit. As shown by the detailed regulations discussed above, it is unlikely that a non-efficacious or unsafe investigational device would survive FDA review.

Moreover, Gile ignores the countervailing public policy of the discovery and development of new products. *See* 21 U.S.C. § 360j(g) (one purpose of investigational device exemptions is "to maintain optimum freedom for scientific investigators"). As explained by the *Slater* court:

> [I]f experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.

961 F.2d at 1334. Thus, state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions.

Finally, Gile argues that the district court's grant of summary judgment based on federal preemption encompassed both forum and claim preemption, leaving her without a remedy. She contends that public policy disfavors preemption of common law where no remedies are available to consumers injured by the unreasonable conduct of a manufacturer. However, Congress has the power to displace state tort law remedies, and clearly did so by enacting the MDA. *See e.g., Stamps*, 984 F.2d at 1421 (citing *Chicago &*

N.W. Transp. Co. v. Kalo Brick & Tile, Co., 450 U.S. 311, 331 (1981)). Moreover, Gile is not precluded from asserting a right of redress in the state forum because her claims against her physician are not preempted under the MDA. *See Slater*, 961 F.2d at 1334; *Hunsaker*, 818 F. Supp. at 751. Thus, despite her arguments to the contrary, Gile is not left without a remedy because she may still pursue her claims, if any, against her physician in state court.

V.

There being no genuine issues as to any material facts in this case, the district court committed no error in rendering summary judgment in favor of ORC as a matter of law. Accordingly, the judgment of the district court in favor of Optical Radiation Corporation will be affirmed.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

APPENDIX C — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY FILED AUGUST 25, 1993

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 92-2957 (GEB)

HELEN GILE,

Plaintiff,

vs.

OPTICAL RADIATION CORPORATION, ET AL.,

Defendants.

ORDER

This matter having come before the Court on motion of defendant Optical Radiation Corporation; and the Court having considered the written submissions and oral argument of counsel for the parties; and good cause having been shown,

Appendix C

IT IS on this *23rd* day *August,* 1993,

ORDERED that the complaint filed by Helen Gile be and hereby is dismissed with prejudice. *Summary Judgment is granted for the reasons set forth on the record.*

s/ Garrett E. Brown
GARRETT E. BROWN, U.S.D.J.

APPENDIX D — TRANSCRIPT OF DECISION DATED AUGUST 23, 1993

Case Number CV 92-2957

402 East State Street
Trenton, New Jersey

August 23, 1993

HELEN GILE,

Plaintiff,

versus

OPTICAL RADIATION, ET AL,

Defendant.

TRANSCRIPT OF DECISION ONLY
BEFORE THE HONORABLE GARRETT E. BROWN
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For Helen Gile: Garruto, Galex & Cantor
By: RICHARD GALEX, ESQUIRE

For Optical Radiation: McCarter and English
By: JOHN FINN BRENNER, ESQUIRE

Audio Operator: Bill Carothers

Appendix D

Proceedings recorded by electronic sound recording, transcript produced by transcription service.

(As requested, only the Court's decision is transcribed)

THE COURT: Let me see if I can rule at the present time, if you'll just remain.

I have reviewed the briefs and documents submitted by the parties and heard the argument that they have made Counsel for the plaintiff asserts that for me to disagree with the decisions of all the Courts that have considered the preemptive effect of Section 360 involving intraocular lenses would be an act of judicial courage. Now, judicial courage, as I reminded counsel in the other case, is not a license for error or a warrant to ignore clear provisions of law.

Now, counsel relies upon one decision, the *Mitchell case — Mitchell versus I.O. Lab Corporation,* 700 Fed. Supp. 877, Eastern District of Louisiana, 1988 and would ask me to ignore the *Slator* and *Honziger* (phonetics) cases. *Slater* and *Honziger* both reviewed *Mitchell,* and they found it wrongly decided, and rejected it. I must say I concur with *Slater* and *Honziger.* I find them persuasive. *Mitchell,* as counsel for the defense notes, is one page in length and is five years old, and it stands alone in its reading of Section 50.20. I do not find it to be persuasive.

In 1976, the Congress promulgated the Medical Device Amendments to the Food and Drug and Cosmetic Act of 1938, which was codified in 21 U.S. Code Section 301 et seq. The amendments were drafted to encourage scientific advancement in the area of medical devices. They empowered the Food and Drug Administration with regulatory authority over such devices and the Medical Device Amendment, referred to by the parties as the

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MDA, authorized the FDA to implement regulations which proscribed states from subjecting such investigational devices to quote, "Any requirement, one, which is different from or in addition to, requirement applicable under the Food, Drug, and Cosmetic Act to the device and which, two, relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device," 21 U.S. Code Section 371(A), 1992).

The FDA issued investigational device exemption regulations for replacement lenses, intraocular lenses to replace an eye's natural lens damaged by cataract, CFR — 21 CFR Section 813, et seq.

To investigate the lenses' safety and efficacy, the FDA, pursuant to 21 U.S. Code Section 360(J)(G) exempted these medical devices from compliance with the Food, Drug, and Cosmetic Act during the pendency of the investigation.

On September 17th, 1981, the FDA approved the clinical investigation of Optical Radiation Corporation's, which is the defendant here, UV 11 H Intraocular lens. According to the affidavit of Enid Rocow (phonetic), Vice President of Compliance at Optical Radiation Corporation, which the parties refer to as ORC at paragraph 2.

By December of 1986, UV 11 H lens was the subject of a clinical investigation to ascertain its safety and efficacy, according to paragraph 3 of that affidavit. According to the complaint, on December 5th, of 1985, the plaintiff here, Helen Gile, underwent cataract surgery. Dr. Henry Scimeca, S-c-i-m-e-c-a, implanted into the interior chamber of her eye an ORC UV 11 H lens. Prior to the surgery, she signed a consent form in which she gave informed consent to the implantation of the investigational medical device.

Appendix D

Dr. Scimeca was a clinical investigator registered under the MDA to carry out the safety and effectiveness study of the ORC lens.

On September 16th, 1987, after numerous complications, the ORC lens had to be surgically removed from the plaintiff's eye. Plaintiff has sued ORC on various theories of state tort law.

The defense seeks summary judgment, which, as we know, under Rule 56 of the Federal Rules of Civil Procedure, may be granted only if there's no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. The Supreme Court trilogy of *Celotex versus Catrit* (phonetic), 477 U.S. 317, 322, 1986, *Matshusita versus Zenith,* 475 U.S. 574, 1986, and *Anderson versus Liberty Lobby,* 477 U.S. 242 are well known.

In a summary judgment motion, the non-moving party receives the benefit of all reasonable doubt and any inferences drawn from the underlying facts. If the non-moving party bears the burden of proof at trial as to a dispositive issue, Rule 56(E) requires him to go beyond the pleadings and designate specific facts showing a genuine issue for trial. Issues of material fact are genuine only if the evidence is such that a reasonable jury could return a verdict for the non-moving party.

Now, in this case, the defendant, ORC, seeks summary judgment asserting that the plaintiff's various state tort law claims concerning the investigational medical device are preempted by the MDA, the Medical Device Amendment that I referred to before.

Now although the 3rd Circuit does not address this specific

preemption issue, both the 1st and 7th Circuits have held that state tort law claims involving investigational medical devices are preempted by the MDA. And the parties refer to these cases in their briefs, *King versus Collagen,* C-o-l-l-a-g-e-n, *Corporation,* 983 Fed 2d, 1130, 1st Circuit, 1993. *Slater versus Optical Radiation Corporation,* 961 Fed 2d. 1330, 7th Circuit, cert denied, 113 Supreme Court, 327, 1992.

Moreover, this District has similarly concluded in the decision S-p-y-c-h-l-a. *Spychala versus G.D. Serle Company* (phonetic), 705 Fed Sup, 1024, District of New Jersey, 1988. That state law claims effecting medical devices are preempted by the MDA.

Slater is a case factually analogous to this case. The 7th Circuit there addressed the preemptive powers of the MDA, 961 at 1136. Plaintiff had the cataract removed and an ORC intraocular lens, the same one referred to here, implanted. The lens received investigation device exemptions, according to the MDA, and following surgical implant, she experienced complications, and the implant had to be removed. Similar to this case, the plaintiff in *Slater* filed suit against ORC under various state tort claims.

Now, the 7th Circuit there addressed the Federal preemption issue and noticed that the MDA investigational device exemption regulations were promulgated to encourage scientific innovation by exempting promising medical devices from the customary requirement of establishing the efficacy and safety of such a device before it can be sold.

The *Slater* Court went on to state that, "Even if experimental procedures are subject to hindsight evaluation by juries so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments and patients will suffer," that's at page 1334.

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Thereafter, the 7th Circuit held the theory underlying the complaint is that the design of the — it was the ORC lens was not sufficiently safe and effective to allow it to be used on human beings. This theory set-up a direct collision with Federal policy. The FDA decided whether rightly or wrongly, but pursuant to regulations, the validity of which the plaintiff does not question, that the ORC lens could be sold subject only to the requirements procedural in character and so far as appears fully complied with, designed to assure that this experimental distribution was, in fact, a worthwhile experiment.

The plaintiff wishes, in the name of the state tort law, to impose additional requirements, namely that the ORC lens have had designed characteristics that lacked (sic), and this engrafting of additional requirements relating to the safety or effectiveness is forbidden by the preemption provision in the Medical Device Amendment, that's at page 1333.

The 7th Circuit has expressly proclaimed all state tort causes of action concerning investigation of medical devices, including ORC's intraocular lens, are preempted by Federal law. See also *King* at 983, Fed 2d, 1136 where the 1st Circuit stated that, "A finding of negligence would force the manufacturer to alter these aspects of the medical device in response to the finding of liability, or be subject to liability. Either result would impose an additional or different state requirement upon the design, manufacturer and marketing and sale of the medical device."

Now, in dictum, this Court also addressed the MDA's preemptive authority over investigational medical devices, as I said before, *Spychala versus G.D. Serle Company,* 705 Fed Sup. 1024, 1026, there Judge Barry (phonetic) was confronted with the issue of whether an experimental drug was exempt from state tort

law claims making a distinction between investigative drugs and medical devices. She stated that, quote, "The expressed preemptive power of MDA, Section 360(k) applies only when the state law claims involve medical devices and not prescription drugs. It is clear, at least to me, that the CU 7 IUD is regulated by the FDA as a drug and falls into category of drug, IUDs, which were not reclassified under the Medical Device Amendment," that's at page 1029.

I find the *Slater* and *King* decisions to be persuasive. The *Mitchell* decision not to be persuasive. The MDA expressly preempts state tort law claims as requirements. I find the argument by the plaintiff that state tort law actions are not requirements to be without merit. And I must find that the MDA expressly preempts state law claims in regard to investigational medical devices of which the ORC device is one. And I must grant ORC's motion for summary judgment.

Let's see. Now, we have a form of order submitted here by the defense.

(Pause)

THE COURT: This matter having come before the Court on motion of the defendant, Optical Radiation Corporation, the Court having considered the written submissions and oral argument of counsel for the parties, and good cause having been shown, this is the 23rd day of August, 1993, ordered that the complaint filed by Helen Gile be, and hereby is dismissed with prejudice, and I would add also counsel's summary judgment is granted for the reasons set forth on the record.

(Conclusion of decision)

APPENDIX E — FIRST AMENDED COMPLAINT AND JURY DEMAND OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY DATED APRIL 28, 1993

GARRUTO, GALEX AND CANTOR P.C.
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RG 9050

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 92-2957 (GEB)

CIVIL ACTION

HELEN GILE,

Plaintiff(s),

vs.

OPTICAL RADIATION CORPORATION XYZ COMPANIES, #1 through #5 and JOHN DOES #1 through #5,

Defendants.

FIRST AMENDED
COMPLAINT AND JURY DEMAND

The plaintiff, Helen Gile, residing at Laurel Run Apartments, Bordentown, Burlington County, New Jersey complaining of the defendants herein, say:

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FIRST COUNT

1. The defendant, Optical Radiation Corporation, distributes its lenses into the stream of commerce in New Jersey.

2. The aforementioned lenses are distributed by the XYZ Company, whose true identity is unknown to the plaintiff. This company was careless and negligent in the manner in which it distributed the lenses by failing to give adequate notice and warnings to physicians and patients concerning the defective nature of the Model UV11H1 lens.

3. On or about the 5th day of December 1985, the plaintiff, Helen Gile, submitted herself to the medical care and attention of Dr. Scimeca, for the purpose of cataract removal and intraocular lens implant.

4. On or about the aforementioned date, Dr. Scimeca did surgically implant an Intraocular Lens into the plaintiff's left eye, said lens having been manufactured by Optical Radiation Corporation.

5. At all times mentioned herein the defendant, Optical Radiation Corporation, negligently designed, manufactured, and distributed an Intraocular Lens known as Model No. UV11H1.

6. The defendant, Optical Radiation Corporation is an out of state corporation doing business in the State of New Jersey.

7. At all times mentioned herein the defendant, Optical Radiation Corporation and the XYZ Companies, whose true identities are unknown to the plaintiff, were careless and negligent with reference to the design, manufacture, distribution and

dissemination of medical information concerning the aforementioned Intraocular Lens. The aforementioned lens was not fit for its intended purpose and the defendants did breach their warranties of merchantability, both expressed and implied and the aforementioned lens was not fit for its intended purpose. Furthermore, the defendants failed to warn the plaintiff, either directly or through the surgeon of the risks to the plaintiff of implanting the aforementioned lens into the plaintiff's body. The defendants are strictly liable in tort for their failure to warn of the dangerous design and condition of their lens and of the injuries that could occur.

8. The defendants, Optical Radiation Corporation and the XYZ Companies, whose true identities are unknown, did manufacture, distribute and sell Model No. UV11Hl Anterior Chamber Intraocular Lens which was defective in design and manufacturing causing excessive movement, irritation, vaulting and difficulty in removing which in turn caused injury to the plaintiff's eye. The defective design caused numerous injuries. Sometime after the insertion of the aforementioned lens, plaintiff started to manifest signs of an ongoing and continuous injury and deterioration of the anatomical structure of her eye. The injury occurred not only upon insertion of the lens, but on a continuous basis thereafter as the defective lens continued to injure the plaintiff and cause a deterioration of the plaintiff's sight.

9. This Intraocular Lens was introduced into the stream of commerce without adequate study or testing and was left on the market despite scientific evidence indicating that the lens was defective and could cause injury to the user.

10. As a direct and proximate result of the joint and several negligence of the defendants, plaintiff was caused to suffer great

pain and will continue to suffer great pain in the future; she was caused to expend large sums of money for medical care and treatment and will continue to expend large sums of money for medical care and treatment in the future; she was caused to suffer permanent injury.

WHEREFORE, plaintiff demands judgment against the defendants jointly, severally or in the alternative for damages and costs of suit.

SECOND COUNT

1. The plaintiff repeats the allegations contained in the First Count of the Complaint as if set forth at length herein.

2. The defendants, John Does, are physicians and/or scientists employed by the defendants, optical Radiation Corporation, and XYZ Companies and their identities are unknown to the plaintiffs at this time.

3. The aforementioned John Does were careless and negligent with reference to the manner in which they designed and manufactured the aforementioned Intraocular Lens and further were careless and negligent with reference to the manner in which they designed and manufactured the aforementioned Intraocular Lens and further were careless and negligent with reference to the manner in which they marketed the aforementioned lens without giving adequate warning and notice to the doctor and patient concerning the use of defective lens.

4. As a direct and proximate result the defendants' joint and several negligence, the plaintiff was caused to suffer great pain and will continue to suffer great pain in the future; she was caused to

expend large sums of money for medical care and treatment and will continue to expend large sums of money for medical care and treatment in the future; she was caused to suffer permanent injury.

WHEREFORE, plaintiff demands judgment against the defendant jointly, severally or in the alternative for damages and cost of suit.

THIRD COUNT

1. The plaintiff repeats the allegations contained in the First and Second Counts as if set forth at length herein.

2. At all times mentioned herein the defendant, Optical Radiation Corporation, knew or should have known of the inherent risks in the use of its Intraocular Lens and it withheld information concerning the risks and hazards inherent with reference to the use of these lenses despite the fact that there was a marketable and feasible alternative.

3. The continued sale of the aforementioned lens despite warnings from various physicians who advised the defendant corporation, caused irreparable injury to the plaintiff and defendant's conduct was grossly negligent and was also based upon misrepresentations of fact to the general public.

4. As a direct and proximate result of the defendant intentional acts of withholding information from the public and making various misrepresentations concerning the quality of the Intraocular Lens, plaintiff was caused to suffer great pain and will continue to suffer great pain in the future; she was caused to expend large sums of money for medical care and treatment and will continue to expend large sums of money for medical care and treatment in the future; she was caused suffer permanent injury.

Appendix E

WHEREFORE, plaintiff demands punitive damages together with interest, costs and attorneys fees.

FOURTH COUNT

1. The plaintiff repeats the allegations contained in the First, Second and Third Counts as if set forth at length herein .

2. As a direct and proximate result of the implantation of the intraocular lens into the plaintiff's eye, she was compelled to undergo medical procedures and will in the future be compelled in the future to undergo lifetime medical surveillance and/or monitoring of her eyes so as to detect and treat various medical conditions and complications which are known to arise from the use of the lens.

3. Additionally, plaintiff has incurred various hospital and/or medical and/or diagnostic expenditures in connection with the original implantation of the intraocular lens and the defendant's acts, omissions, carelessness and negligence may in the future cause the plaintiff to incur additional physician, hospital, diagnostic, laboratory, and other health care expenses associated with the diagnosis and treatment of ophthalmologic conditions caused by the use of the intraocular lens.

WHEREFORE, plaintiff demands judgment against the defendant for money damages to cover the lifetime costs of medical surveillance, costs of original implantation, and/or present and/or future explanation and/or surgical replacement of the implant and the costs of any and all present and future diagnostic and/or medical and/or providers of health care of the plaintiff together with interest, costs and attorneys fees.

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FIFTH COUNT

1. The plaintiff repeats the allegations contained in the First, Second, Third and Fourth Counts as if more fully set forth herein.

2. At all times mentioned herein the defendants did depart from the requirements required of them in seeking pre-market approval of the lens and further they did intentionally and carelessly fail to properly monitor the "investigational study" and further did either intentionally or negligently fail to properly and adequately report the results of the investigational study to the plaintiff's physicians, to the FDA, to the medical community and to the plaintiff, said conduct caused the plaintiff to give uninformed consent to participate in the investigational study and further did leave the plaintiff at risk for more injury to her eyes as a result of the failure to monitor and/or remove the lens in a timely manner.

3. As a direct and proximate result of the defendants willful and negligent failure to comply with industry and government standards and based upon the defendants failure to comply with and properly report the results of its investigational study, plaintiff was caused to sustain severe personal injury; she has and will be caused to expend large sums of money for medical care and treatment; she was caused to sustain permanent injury.

WHEREFORE, plaintiff demands judgment against the defendants for both punitive and compensatory damages, together with interest, costs, and attorneys fees.

JURY DEMAND

The plaintiff demands a trial by jury as to all issues stated herein.

Appendix E

DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to Rule 4:10-2(b), demand is hereby made that Defendant disclose to Plaintiff's attorneys whether there are any insurance agreements or policies under which any person or firm carrying on an insurance business may be liable to satisfy part or all of a Judgment which may be entered in this action or indemnify or reimburse for payments made to satisfy the Judgment and provide plaintiff's attorneys with true copies of such insurance agreements or policies, including but not limited to any and all declaration sheets. This demand shall be deemed to include and cover not only primary coverage but also any and all excess, catastrophe and umbrella policies.

GARRUTO, GALEX AND CANTOR
Attorneys for Plaintiff(s)
By: s/ Richard Galex
RICHARD GALEX

Dated: April 28, 1993

Appendix E

CERTIFICATION PURSUANT TO R. 4:5-1

RICHARD GALEX, does hereby certify as follows:

1. I am an attorney at law of the State of New Jersey, and an attorney in the law firm of Garruto, Galex and Cantor P.C., attorneys for the plaintiffs, and am familiar with the above captioned matter.

2. To the best of my knowledge, information and belief, there is no other action pending about the subject matter of this Complaint in any court or arbitration proceeding nor are there any other persons known to me who should be added as parties to this matter nor are there any other actions contemplated.

3. I do hereby certify that the foregoing statements made by me are true to the best of my knowledge and if knowingly made false, I am subject to punishment.

s/ Richard Galex
RICHARD GALEX

Dated: April 28, 1993

APPENDIX F — CONSTITUTIONAL AMENDMENTS AND STATUTES INVOLVED

AMENDMENT I.

Freedom of religion, speech and press; peaceful assemblage; petition of grievances

Congress shall make no law respecting an establishment of religion or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

* * *

AMENDMENT VII.

Civil trials

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

* * *

AMENDMENT X.

Reserved powers to states

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Appendix F

* * *

THE PUBLIC HEALTH CIGARETTE SMOKING ACT

15 U.S.C. § 1334. Preemption

* * *

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act [15 USCS §§ 1331 et seq.].

* * *

THE FOOD, DRUG AND COSMETIC ACT

21 U.S.C. § 360k. State and local requirements respecting devices

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) Exempt requirements. Upon application of a State or a

political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) The requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

* * *

21 U.S.C. § 360h(d)

* * *

(d) Effect on other liability. compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

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* * *

21 U.S.C. § 360pp(e) Compliance with regulations

* * *

(e) Compliance with regulations

Except as provided in the first sentence of section 360ss of this title, compliance with this part or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

21 U.S.C. § 360pp(f) Additional remedies

* * *

(f) Additional remedies

The remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law.

* * *

21 U.S.C. § 360g(e) Remedies.

* * *

(e) Remedies

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

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* * *

FDA EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

21 C.F.R. § 808.1(d)(1)

* * *

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

* * *

21 C.F.R. § 808.1(d)(6)(i)

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacturer of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

* * *

N.J. PRODUCTS LIABILITY STATUTE

N.J.S.A. § 2A:58C-2. Liability of manufacturer or seller; proof by preponderance of evidence product not reasonably fit, suitable or safe for its intended purpose

A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

* * *

FDA SPONSOR RESPONSIBILITIES

21 C.F.R. § 813.25(a)(11) Investigational plan.

(a) The investigational plan or the investigational study of an intraocular lens shall include the following:

* * *

(11) The plan for obtaining informed consent from subjects and copies of all informational materials to be given to subjects, including all forms and materials to be used in obtaining such consent;

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* * *

FDA INFORMED CONSENT

21 C.F.R. § 50.25(c)

(c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

* * *

FDA SPONSOR RESPONSIBILITIES

21 C.F.R. § 813.46(c)

* * *

(c) Upon discovery by the sponsor that the investigator has not complied with the requirements of this subpart and Subpart G of this part or his agreement under § 813.43(b), the sponsor shall secure the investigator's compliance or discontinue shipments to the investigator and may require the investigator to return or otherwise make appropriate disposition of the lens in accordance with the requirements of § 813.107(b), and may suspend or terminate any study being performed by the investigator for the sponsor.

* * *

APPENDIX G — CATARACT OPERATION CONSENT FORM DATED MARCH 26, 1993

INFORMED CONSENT FOR CATARACT OPERATION AND/ OR IMPLANTATION OF INTRAOCULAR LENS

INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent. You have the right to ask questions about any procedure before agreeing to have the operation.

Except for unusual problems, a cataract operation is indicated only when you cannot function adequately due to poor sight produced by the cataract. You must remember that the natural lens within your own eyes with a slight cataract, although not perfect, has some distinct advantages over any man-made lens.

After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation — based on your own visual needs, and medical considerations, unless you have unusual cataract that may need immediate surgery.

ALTERNATIVE TREATMENTS

You may decide not to have a cataract operation at all. However, should you decide to have an operation, you should understand completely the three methods of restoring useful vision after the operation. One (1) of the 3 methods listed below is required to correct your vision after surgery:

1. Spectacles (glasses) — Cataract spectacles are usually thicker

and heavier than regular eyeglasses. Cataract spectacles increase the size of objects by about 25%. Clear vision is obtained only through the central part of cataract spectacles. This means you must learn to turn your head to see clearly on either side. Cataract spectacles usually cannot be used if a cataract is only in one eye (and the other is normal) because they may cause double vision.

2. Contact Lens — A hard or soft contact lens increases the size of objects only about 8%. Handling of a contact lens can be difficult for some individuals. Most lenses must be inserted and removed daily and not everyone can tolerate them. For near tasks, eyeglasses (not cataract spectacles) may be required in addition to contact lenses.

3. Intraocular Lens— This is a small plastic artificial lens with plastic supports which is surgically placed inside your eye permanently. The intraocular lens appears to show no change in the size of the objects you see. Conventional eyeglasses (not cataract spectacles) are usually needed in addition to an intraocular lens to give you the best vision possible.

Some intraocular lenses are investigational devices. Other intraocular lenses have been clinically proven as safe and effective. Your doctor can provide information to help you decide which intraocular lens is right for you, should you choose this method of restoring useful vision after the cataract operation.

CLINICAL INVESTIGATION

The United States Food and Drug Administration, in response to Congressional mandate, is requiring an extensive clinical

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investigation of intraocular lenses to establish facts about the safety and efficacy of these lenses. You have been asked to take part in this study because your doctor considers you a good candidate to help evaluate the intraocular lenses. The study involves a minimum one-year observation of the results of your surgery. The purpose of this observation is to compare in a similar group of patients the differences, if any, in eyes with and without lens implantations. Information about the results of your surgery will be made available to the Food and Drug Administration and to the lens manufacturer. The confidentiality of your medical records will be maintained by your doctor, the lens manufacturer, the hospital and the Food and Drug Administration, and your personal records will not be released or revealed beyond the scope of this study without your permission. If for any reason you wish to decline participation in the study, you may do so without at all affecting your future medical care. It is estimated that over 500,000 individuals have received intraocular lenses as patients in this study. All questions pertinent to this investigation and concerning your rights as a study patient should be directed to your doctor.

CONSENT FOR OPERATION

In giving your permission for a cataract extraction and/or for the implantation of an intraocular lens in your eye, it is very important that your understand the following information:

1. Your participation in this study is completely voluntary. You will receive no compensation for participation in this study and you will suffer no penalty or loss of benefits as a result of study discontinuation. You may withdraw from the study at any time without consequence to your future medical care.

2. Cataract surgery, by itself, means the removal of the natural

lens of the eye by a surgical technique. In order for an intraocular lens to be implanted in your eye, you must have cataract surgery performed either at the time of the lens implantation or before lens implantation.

3. If an intraocular lens is implanted, it is done by surgical method. It is intended that the small plastic lens with the plastic supports will remain in your eye permanently.

4. The results of the cataract operation cannot be guaranteed in your or anyone's case.

5. At the time of surgery, your doctor may decide not to implant an intraocular lens in your eye even though you may have given prior permission to do so.

6. *Complications of Surgery to Remove the Cataract:* As a result of the surgery, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. Complications may include hemorrhage (bleeding), loss of corneal clarity, infection, detachment of the retina, glaucoma, and/or double vision. These and other complications may result in poor vision, total loss of vision or loss of the eye. These types of complications may occur whether or not an intraocular lens is implanted.

7. *Specific Complications of Lens Implantations:* Insertion of an intraocular lens may induce complications which otherwise would not occur. In some cases complications may develop during surgery from implanting the lens, or days, weeks, months or even years later. Complications may include loss of corneal clarity, infection, uveitis, iris atrophy, glaucoma, bleeding in the eye, inability to dilate the pupil, dislocation of the lens and retinal detachment.

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8. At some future time, the lens implanted in your eye may have to be repositioned or removed surgically.

9. *Complications of Surgery in General:* As with all types of surgery, there is the possibility of other complications due to anesthesia, drug reactions or other factors which may involve other parts of your body, including a possibility of brain damage or even death. Since it is impossible to state every complication that may occur as a result of surgery, the list of complications in this form is incomplete. In the event of a study-related injury, you should contact your doctor immediately for medical care. IOLAB does not provide financial compensation and has no policy to provide medical or health care to any IOL recipient.

PATIENT STATEMENT

The basic procedures of cataract surgery and the advantages and disadvantages, risks and possible complications of alternative treatments have been explained to me by my doctor. Although it is impossible for my doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction. I understand that the implanting of this intraocular lens in my eye is part of a clinical investigation and that periodic visits to the doctor by me will be required for at least one year to evaluate the results of my operation. I give permission for medical data concerning my operation and subsequent treatment to be submitted to the lens manufacturer and to the FDA for the clinical study described. I understand I may withdraw from the clinical study at any time without jeopardizing may future medical care. In signing this informed Consent for Cataract Operation and/or Implantation of Intraocular Lens, I am stating that I have read this informed consent (or it has been read to me). I

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fully understand the consent I am giving, and the possible risks, complications and benefits that can result from the surgery.

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If I decide to have an operation, I agree to have the type of operation listed below which I have indicated by my signature:

(1) I wish to have a cataract operation without an intraocular lens implantation.

Patient's signature _____

(2) I wish to have a cataract operation with an intraocular lens implantation.

Patient's signature *Helen Gile*

(3) Since my cataract was previously removed and I have been informed by the doctor that my eye is medically acceptable for lens implantation, I wish to have an intraocular lens implanted.

Patient's signature _____

Patient's Name (Printed) *Helen Gile* Age *65*

Date *3/15/85* Time *2:31 P.M.* Place *RUEA*

Witnesses' Signature *Janet L. Hunt*

Doctor's Signature *illegible*

INFORMATION FROM THE INTRAOCULAR LENS MANUFACTURER — IOLAB

The above information is a *minimum* information required by the United States Food and Drug Administration to be furnished to you for your consent for the operation and the extensive clinical

investigation being made of intraocular lenses to determine facts about safety and efficacy.

Be Informed — Your physician will furnish any additional information you require to be certain you are fully informed about the operation, the lens and the investigation.